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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,065	06/22/2005	Satoshi Wanezaki	2005-0999A	2606

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
WEIER, ANTHONY J	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,065	WANEZAKI ET AL.	
	Examiner	Art Unit	
	Anthony Weier	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/05, 9/21/05, 12/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 4 of copending Application No. 10/559730. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims call for particular solubility values, amounts of solvent used, and narrowing of the amounts of saponin and malonyl isoflavoneglycoside over those set forth in 10/559730. Such determination of particular ranges of amounts would have been well within the purview of one skilled in the art at the time of the invention through routine experimental optimization. The instant claims 1-4 and 7 further call for the source of said composition to be soybean hypocotyls as well as the amounts of same included. It is not seen where the use of such source would make for a patentable distinction. It would have been further

obvious to have arrived at such source as a matter of preference depending on, for example, the particular source that is readily available, most inexpensive, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 5, 6, and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of copending Application No. 10/507637. Instant claims 5, 6, and 8 are generic to or fully encompass claim 23 of copending Application No. 10507637. In particular, claim 23 recites a process which is more specific than that of instant claims 5, 6, and 8 but well within the scope of claims 5, 6, and 8.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04266898.

JP 04266898 discloses an isoflavone containing composition comprising malonyl isoflavone glycosides and due to the similarity in extraction of soybean hypocotyls using aqueous ethanol to that use din the instant claims, it is inherent that same would also include an amount of saponins in the amounts as called for in the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al taken together with Matsuura et al and Shiraiwa et al.

Bombardelli et al discloses a composition containing saponins and isoflavones (including malonyl isoflavones) and a method for attaining same by extraction of soybean material (including soybean hypocotyls) using, for example, an ethanol solution (inherently at room temperature) in a concentration of 95% pure ethanol wherein said composition is attained use of absorbents and elution steps to arrive at saponin and isoflavone components that may be combined (see cols 6 and 7). It should be noted that said extract is edible and used in pharmaceutical compositions (e.g. Abstract).

The claims differ in the amounts of malonyl isoflavone glycosides and saponins that are provided in the composition attained from such treatment as well as the particular water content of the ethanol solution. It should be first noted that Matsuura et al teaches the antioxidizing and solubility benefits of malonyl isoflavone (e.g. col. 1) and furthermore provides direction as to isolating same from soybean employing extraction, absorbent, and elution steps similar to those of Bombardelli et al. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the amount of malonyl isoflavone in the final product to provide such benefits and to have achieved the amounts as called for in the instant claims through routine experimental optimization. It would have been further obvious to have arrived

at the particular solubility called for in claim 4 by manipulating the amount of said malonyl isoflavone in the final product which is known to have good solubility as a matter of preference depending on the degree of such benefit desired in the final product.

Claims 3 calls for the amount of Group A saponins present in the final product. Shiraiwa et al discloses isolation of Group A saponins using techniques, again, similar to those of Bombardelli et al. Since it is known that Group A possess a particular taste that separates same from the other saponins, it would have been well within the purview of a skilled artisan to adjust and target the particular amount of same present in the final product as a matter of preference depending on the degree of such taste desired or avoided in the final product.

The claims further call for particular processing conditions not expressly articulated in Bombardelli et al (e.g. water in ethanol solution during elution from adsorbent resin). However, such processing conditions would have been well within the purview of a skilled artisan, and it would have been further obvious to have arrived at same through routine experimental optimization.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anthony Weier
Primary Examiner
Art Unit 1794

/Anthony Weier/
Primary Examiner, Art Unit 1794

Anthony Weier
September 28, 2008